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**PATENT APPLICATION**
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| First Applicant: | KHARITONENKOV Alexei | Group Art Unit: - 1647 |
| Serial No.: | 10/587138 | Examiner: - Christine J. Saoud |
| Application Date: | July 21, 2006 | Conf No.: 1688 |
| For: | USE OF FGF-21 AND A THIAZOLIDINEDIONE FOR TREATING TYPE 2 DIABETES | |
| Docket No.: | X16455 | |

## RESPONSE TO RESTRICITION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

## Introductory Comments

This paper is filed in response to the restriction requirement dated April 23, 2008 and for which a response is due on May 23, 2008. Entry of the following election and remarks is respectfully requested. Any fees associated with this amendment may be charged to Eli Lilly Account No. 05-0840.

Claims 1-8 are currently pending. The Examiner has made a restriction requirement under PCT Rule 13.1 and 13.2 maintaining that the application contains claims directed to more than one species of the generic invention and that these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept.

The species are as follows: rosiglitazone and pioglitazone.

The claims are deemed to correspond to the species listed above in the following manner:
Claims 1-7 are directed to use of rosiglitazone;
Claims 1-6 and 8 directed to use of pioglitazone;
Claims 1-5 are deemed generic.

Applicants provisionally elect, with traverse, the species rosiglitazone corresponding to claims 1-7.

## Remarks

Applicants respectfully submit that the invention as claimed meets the unity of invention requirements of PCT Rules 13.1 and 13.2 and, therefore, the Examiner's requirements for restriction of the invention and an election of species are improper. The Examiner concludes that the present application contains claims directed to more than one species of the generic invention and therefore fails to meet the unity of invention requirements of PCT Rules 13.1 and 13.2 because "the species lack the same or corresponding special technical feature [because] they are distinct compounds and have unique structures and therefore do not share the same or corresponding special technical feature" (Office Action, first paragraph on page 3). Applicants respectfully disagree with the Examiner's conclusion and reasoning in this matter because the Examiner has improperly interpreted PCT Rule 13.2 and has not accurately construed the invention as claimed.

PCT Rule 13.2 states that the requirement of unity of invention is fulfilled "when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". (PCT Rule 13.2, first sentence, emphasis added) "[T]he requirement of a technical interrelationship and the same or corresponding technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature." (M.P.E.P., Administrative Instructions Under the PCT, Annex B, Al-59, paragraph (f)) The alternatives are regarded as being of a similar nature where: "all alternatives have a common property or activity" (Id., paragraph (f)(i)(A)); and "...all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains". (Id., paragraph (f)(i)(B)(2)) "[T]he words 'recognized class of chemical compounds' mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved." (Id., paragraph (f)(iii)).

The present application contains claims directed to a method of treating type 2 diabetes or metabolic syndrome by administering a combination of FGF-21 and a thiazolidinedione.

Thiazolidinediones are a class of compounds approved for the use in the treatment of type 2 diabetes. Rosiglitazone and pioglitazone are antidiabetic medicines that belong to the class 'thiazolidinediones'. Both rosiglitazone (available as Avandia®) and pioglitazone (available as Actos ®) are approved treatments for type 2 diabetes and therefore they are a 'recognized class of chemical compounds' that provide an expectation from the knowledge in the art that they will behave in the same way in the context of the claimed invention. Accordingly, they share the same special technical feature as a therapeutic agent for the treatment of type 2 diabetes. Moreover, the single general inventive concept under PCT 13.1 is the combination therapy with FGF-21 and *any* thiazolidinedione.

Applicants respectfully request reconsideration regarding the election of a single species from rosiglitazone and pioglitazone because the Examiner could readily access information regarding the use of the compounds and there is a minimal additional burden on the Examiner to examine the elected compounds in combination therapy with FGF-21.

If the Examiner's decision is to maintain the improper restriction requirement and reject Applicants' arguments, then Applicants elect, solely for purposes of examination, the species of rosiglitazone corresponding to Claims 1-7, with traverse.

The Applicants urge the Examiner to call the Applicant's attorney at (317) 276-6501 if a telephone conversation would be helpful in expediting prosecution of this case.

Respectfully submitted,

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